Date: November 12, 2013

510(k) Summary

3-1. 510(k) owner (submitter)

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in US	Goro Asanuma KURARAY AMERICA, INC. 33 Maiden Lane, 6th Floor, New York, NY 10038 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	K-ETCHANT Syringe
2) Classification name	Resin Tooth Bonding Agent (21 CFR section 872.3200 Product code: KLE)
3) Common name	Phosphoric Acid Gel

3-3. Predicate device

1) K-ETCHANT GEL	510(k) Number:	K062409
	Classification:	Tooth Shade Resin Material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.
2) UNI ETCH	510(k) Number:	K101485
	Classification:	Resin Tooth Bonding Agent
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Bisco, Inc.
3) PANAVIA F 2.0	510(k) Number:	K032455
	Classification:	Dental Cement
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	Kuraray Noritake Dental Inc.
4) CLEARFIL AP-X	510(k) Number:	K012740
	Classification:	Tooth Shade Resin Material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.
5) CERABIEN ZR	510(k) Number:	K031968
	Classification:	Porcelain Powder for clinical use
	Product Code:	EIH
	21 CFR Section:	872.6660
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device is an etching gel that consists of 35% phosphoric acid aqueous solution and colloidal silica. It allows for precise and selective placement thanks to its flowable but not runny consistency.
This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.
This device is filled in a syringe made of polypropylene and polyethylene. The etching agent is applied to tooth surface through a nozzle attached to tip of the syringe. The nozzle is made of polypropylene and stainless steel(SUS304).

3-5. Statement of Intended Use

1. Etching of enamel and dentin
2. Cleaning of dental restorative materials

3-6. Substantial Equivalence Discussion

1) Intended uses
The intended use of the subject device was written up based on that of the predicate devices. Therefore, the intended use of the subject device is substantially equivalent to that of the predicate devices.

2) Chemical ingredients/ Safety
The subject device, K-ETCHANT GEL and UNI ETCH contain similar amount of phosphoric acid.
All ingredients in the subject device have been used in the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
In conclusion, it can be said that the safety of the subject device is substantially equivalent to that of the predicate devices.

3) Technological characteristics/ Effectiveness and Performance
K-ETCHANT GEL, one of the predicate devices, is filled in a bottle, while the subject device is filled in a syringe as the other predicate device, UNI ETCH. The dimension and materials of the subject device's syringe are similar as those of the UNI ETCH's.

Both the subject device and UNI ETCH are directly applied to tooth surface through a nozzle attached to the tip of syringe. On the other hand, K-ETCHANGT GEL is once dispensed to a mixing dish and applied to tooth surface with a small brush.

Since there have not been any international standards concerning performance of this type of device, certain tests were performed on this device considering its intended uses, in comparison with the predicate devices.
The test items and brief description of the results are as follows.

(1) pH:
It was confirmed that the pH value of the subject device was equivalent to those of the predicate devices.

(2) Enamel and dentin decalcification:
It was confirmed that the etching pattern treated by the subject device was equivalent to those by the predicate devices.

(3) Tensile bond strength of a bonding agent to tooth surface which was etched:
Each tensile bond strength of a bonding agent which had been used after treatment of the subject device was not statistically ($P>0.05$) different from the corresponding measured value of the predicate device.

(4) Tensile bond strength of a bonding agent to various prosthetic restorations which were treated by an etching agent:
Each tensile the bond strength of a bonding agent which had been used after treatment of the subject device was not statistically ($P>0.05$) different from the corresponding measured value of the predicate device.

As the results of the above testings, it was concluded that the effectiveness and performance of the subject device were substantially equivalent to those of the predicate devices.
Accordingly, it was concluded that the effectiveness and performance of the subject device

were substantially equivalent to those of the predicate devices.

3-7. Biocompatibility

The subject device is categorized into the external communicating device that may contact dentin and whose duration of contact is less than 24 hours.
All the chemical ingredients of the subject device are equivalent to those of the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
Accordingly, it was considered that the subject device was substantially equivalent in safety to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Kuraray Noritake Dental Incorporated
C/O Mr. Goro Asanuma
General Manager
Kuraray America, Incorporated
33 Maiden Lane, 6th Floor
New York, NY 10038

Re: K133078
Trade/Device Name: K-ETCHANT Syringe
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 19, 2013
Received: November 21, 2013

Dear Mr. Asanuma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133078

Device Name: K-ETCHANT Syringe

Indications for Use:

1. Etching of enamel and dentin

2. Cleaning of dental restorative materials

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use N/A (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2015.12.20
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